Rational Pharmaceutical Management Plus
Caucasus Workshop on TB Pharmaceutical Management: Trip Report
Tbilisi, Georgia July 26-30, 2004

Thomas Moore
Andrey Zagorskiy

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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

A regular supply of TB medicines is one of the main components of the DOTS and DOTS Plus schemes. RPM Plus conducted a workshop in Tibilisi, Georgia to promote appropriate management of TB medicines in the Caucasus region. 22 participants from the countries of Armenia, Azerbaijan and Georgia participated in the course. The course was co-funded by GTZ and the ICRC.

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Key Words

tuberculosis, TB, pharmaceutical management, FDC, MDR-TB, DOTS, DOTS Plus

Contents

Acronyms

MDR-TB	Multi-drug resistant tuberculosis
FDC	Fixed dose combination products
GLC	Green Light Committee
GTZ	German Technical Development Cooperation
ICRC	International Committee of the Red Cross
DOTS	WHO scheme for controlling TB in national programs
DOTS Plus	Projects to control multi-drug resistant TB which are built on a good DOTS scheme
USAID	U.S. Agency for International Development
TB	Tuberculosis

Background

Tuberculosis (TB) continues to place a heavy burden on the world's poorest countries, despite the fact that established diagnostic procedures, medicines and supplies exist for this disease able to improve health outcomes. Too often, however, program implementation suffers because of lack of access to and appropriate use of pharmaceutical supplies and essential medicines.

The governments of Armenia, Georgia, and Azerbaijan have committed to the adoption of the WHO developed DOTS strategy and have received grants of pharmaceuticals from the Global TB Drug Facility (GDF) and other donors to support the strategy's implementation. Because of rising Multi-drug TB resistance, these countries also intend to apply to the Green Light Committee (GLC) in the near future for technical assistance in establishing a valid DOTS Plus project and to procure multi-drug resistant TB (MDR-TB) drugs at special prices through the GLC process. Understanding that a prerequisite for successful DOTS and DOTS Plus project implementation is an uninterrupted supply of TB drugs, the German technical development cooperation (GTZ) and the International Committee of the Red Cross (ICRC), requested that MSH/RPM Plus conduct a workshop to train participants from the three countries in the appropriate management of first and second-line TB drugs.

The workshop, conducted in Russian in Tbilisi, Georgia on July 26-30, 2004, covered the various components of a successful TB pharmaceutical management system, including selection, procurement, distribution, use, quality assurance and monitoring. The workshop was co-funded by USAID through the RPM Plus program, ICRC and GTZ. Thomas Moore and Andrey Zagorskiy were the workshop facilitators.

Scope of Work

The scope of work was as follows:

1. Brief/debrief USAID/Georgia officials, upon request

2. Facilitate the workshop on the management of first- and second-line TB drugs

Activities

1. Brief/debrief USAID/Georgia officials, upon request

Thomas Moore and Andrey Zagorskiy met with Dr. Gegi Mataradze, USAID Project Management Specialist in Health in Tiblisi on July 29, 2004. RPM Plus updated Dr. Mataradze on the status of the workshop, number of participants (22, see Annex 2) and format of the course and presented a computer disc of the course materials. See Annex 1 for a list of participants.

RPM Plus indicated to USAID that each participant would be leaving the course with a drug management improvement plan which would be carried out upon return to their respective TB programs. The plans include TB drug management weaknesses identified by participants, activities to improve the weaknesses, persons responsible for carrying out the activities and additional resources such as finances and technical assistance needed to complete each activity.

Dr. Mataradze expressed interest in the improvement plans and RPM Plus provided copies to USAID through Dr. Nicholas Nasidze, participant of the workshop and staff of the Medical Service Corporation International company, responsible for carrying out a USAID locally-funded project in TB control.

RPM Plus mentioned the interest of the GTC and the ICRC in conducting a follow-up workshop next year to monitor progress in TB pharmaceutical management in the region. The two organizations will contact the USAID mission about support to co-fund this event.

2. Facilitate the workshop on the management of first- and second-line TB drugs

The course consisted of seven sessions. See Annex 1 for the Agenda and Annex 3 for a synopsis of the sessions. An *Overview* document was sent to participants prior to the workshop describing the format of the course and requesting that they bring program-specific information for use during the practical exercises.

Each session was accompanied by one or more practical activities related to the presented materials. The practical activities allowed participants to assess pharmaceutical management practices within their TB programs. Many of the activities were accompanied by a checklist which could be later used by participants for assessing their TB programs once interventions are put into place. Pharmaceutical management of both first-line and second-line drugs was covered during the course including how to set up DOTS Plus project and how to procure MDR-TB drugs through the GLC.

The last session trained participants how to monitor and supervise their TB pharmaceutical programs through indicators. The practical activity for this session consisted of a field visit to the Georgia national TB program coordinator, central and regional pharmaceutical stores, drug regulatory authorities and TB treatment facilities. In preparation for the field visit, participants chose appropriate indicators, identified exact data needed for calculation of the indicators, and discussed where the data could be accessed. Once the data was collected, the participants then analyzed it, calculated the indicators and prepared a presentation of findings and recommendations for the Georgia TB program. See annex 3 for a list of indicators suggested to participants. A copy of the participants' presentations are available in Russian at the RPM Plus office.

Participant workshop evaluations:

Facilitators provided an evaluation checklist to participants. The didactic presentations, in-class practical exercises and the final field visit were each evaluated by 20 participants. A score of 4 or 5 meant that the session or activity exceeded expectations in terms of understanding and value to their work. The percentage of combined scores of 4 and 5 are reported below. See annex 4 for complete evaluation results including participant responses to general questions.

Session	Percent Choosing 4 or 5
Introduction	90
Activity	85
Selection and Quantification	90
Activity	100
Procurement	95
Activity	75
Quality Assurance	90
Activity	84
Distribution	90
Activity	94
Use	80
Activity	90
Monitoring and Evaluation	85
Field Activity	100
Personal Improvement Plan	95

Collaborators and Partners

Dr. Cornelia Henning, GTZ Georgia
Dr. Shalva Gamtsemlidze, GTZ Georgia
Dr. Phillipe Creac'h, ICRC Georgia

Next Steps

- RPM Plus will work with GTZ and ICRC to plan for the follow-up TB pharmaceutical management workshop in 2005
- Before the end of 2004 RPM Plus will send a data collection instrument to be used by each of the three countries to measure status of TB pharmaceutical management. The findings will be used as baseline—GTZ and ICRC have offered their support in monitoring this data collection survey
- RPM Plus will ask each country to conduct a second data collection survey of the status of TB pharmaceutical management just prior to the follow-up TB pharmaceutical management workshop in 2005—GTZ and ICRC have offered their support to monitor this survey as well
- RPM Plus will provide technical assistance electronically during the two surveys

Annex 1

Agenda

Day	Time	Activity
July 26	9:00–9:30	Welcome and introduction to the course (USAID, ICRC, GTZ, Georgia NTP)
	9:30–10:00	Introduction of presenters and participants
	10:00–10:30	Format of the course
	10:30–11:00	**Break**
	11:00–11:30	**Session 1: Introduction to Management of TB Medicines and Supplies**
	11:30–12:00	Group Activity
	12:00–13:00	**Session 2: Selection and Quantification**
	13:00–14:00	**Lunch**
	14:00–17:00	Group Activity
July 27	9:00–10:30	**Session 3: Procurement**
	10:30–11:00	**Break**
	11:00–12:00	Group Activity
	12:00—13:00	**Session 4: Quality Assurance**
	13:00–14:00	**Lunch**
	14:00–15:00	Group Activity
	15:00–15:45	**Session 5: Distribution**
	15:45–17:00	Group Activity
July 28	9:00–10:00	**Session 6: Use**
	10:00—10:30	Group Activity
	10:30–11:00	**Break**
	11:00–11:30	**Session 7: Monitoring and Evaluation**
	11:30–12:00	Instructions for the monitoring and evaluation exercise
	12:00—16:00	Group Activity—preparing for field visit
	13:00–14:00	**Lunch**
	16:00–17:00	Plenary—review participant field visit plans/data collection instruments
July 29	9:00–13:00	**Fieldwork**
	13:00—14:00	**Lunch**
	14:00–17:00	Group work—analyze data, prepare presentation of findings and recommendations
July 30	9:00–10:30	Plenary—Groups present findings and recommendations
	10:30–11:00	**Break**
	11:00–12:00	Individual work—prepare country plans for Improvement--

Day	Time	Activity
	12:00—12:30	Individual activity-course evaluation
	12:30–13:00	Closing comments
	13:00:14:00	**Lunch**

Annex 2

Workshop Participants

	Armenia -GTZ		E-mail address
1.		GASPARYAN Nelly	
2.		AZNAURYAN Vardan	aznavur2000@yahoo.com
3.	Armenia - ICRC	PETROSYAN Gegham	erevan.ere@icrc.org
4.		HARUTYUNYAN Davit	
5.		HOVANNESYAN Ara	aivanich@freenet.am
6.		BATES Jim	jim_bates@jsi.com
7.	Azerbaijan - GTZ	JAFAROV Shovgi	
8.		ASADOVA Yegana	
9.		MAMMEDOVA Sveta	
10.		GOZALOV Ogtay	gtzhealth1@azeurotel.com
11.	Azerbaijan - ICRC	HAJIEVA Sona	
12.		HUSEYNOV Mushfig	mushfiq69@box..az
13.		HUSEINOV Fizuli	
14.	Georgia - GTZ	GORGASLIDZE Nana	nanagor@rambler.ru
15.		SIKHARULIDZE Rusiko	
16.		BICHASHVILI Eliso	
17.		GAMTSEMLIDZE Shalva	Gtzmed2@geo.net.ge
18.		KAVTARADZE Maia	Gtzmed3@geo.net.ge
19.	Georgia - ICRC	MADZGARASHVILI Mikheil	
20.		ISHKHNELI Kakha	kakha_ishkhneli@yahoo.com
21.		MCHEDLIDZE Givi	
22.	Georgia - MSCI	NASIDZE Nicholas	Nicholas.msci@caucasus.net
23.	MSH	MOORE, Thomas	tmoore@msh.org
24.	MSH	ZAGORSKIY, Andrey	azagorskiy@msh.org
25.	ICRC	Philippe Creac'h	TBI@icrc.org

Annex 3

Workshop Sessions

Session 1: Introduction

This session introduces the concept of pharmaceutical management in general, and management of TB medicines and supplies in particular, emphasizing differences in management from other commodities. The Pharmaceutical Management cycle is used to graphically illustrate the interdependent relationships between various activities in the selection, procurement, distribution, and use of tuberculosis medicines within existing policy and legal framework. Upon completion of this session, the participants have an understanding of the importance of pharmaceutical management for success of TB programs and a framework for analyzing TB medicine policy and management.

Session 2: Selection and Quantification

This session discusses the process of medicine selection for TB programs based on a variety of factors such as cost, resistance to drugs, access to quality medicines, and management and distribution capacity. The five essential first-line medicines recommended by the World Health Organization (WHO) for resource-poor contexts are covered. Selection of medicines for MDR-TB is based on the resistance pattern in the population and results of drug susceptibility tests; typical second-line medicines are presented and discussed. Various packaging types are also demonstrated including fixed dose combination products (FDCs) and patient kits which contain all the medicines needed to fully treat one patient.

This session also introduces three commonly employed quantification methods: the morbidity-based, consumption-based, and adjusted-consumption methods. However, only the morbidity method as recommended by WHO is used to practice calculation of TB drug needs. For this session participants use their own treatment regimens to practice drug needs quantification using the morbidity method..

Session 3: Procurement

This session reviews the standard methods of procurement, the steps in the procurement process and the organizational components that a supply system must have to procure medicines and supplies at the lowest possible cost. Workshop materials emphasize using restricted competitive tenders as the preferred method for procuring TB drugs which requires that a pharmaceutical program pre-qualify TB suppliers. Procedures for procuring 1st and 2nd line TB medicines from UN organizations like Global TB Drug Facility (GDF) and Green Light Committee (GLC) are discussed in detail.

Session 4: Quality Assurance

This session provides a clear definition of quality assurance and expands the participants' global awareness of concerns regarding the use of substandard pharmaceuticals and the causes of their

proliferation as well as an understanding of the determinants of pharmaceutical quality. It emphasizes both **technical** and **managerial** actions as well as different practical approaches that can be employed to assure pharmaceutical quality.

Session 5: Distribution

This session covers the process of distribution which includes receipt of tuberculosis medicines at the port of entry, clearance through customs, and delivery from the central warehouse(s) to depots and health facilities, where the medicines are stored and dispensed to patients. Costs of storage and delivery are discussed and how to minimize these costs whether the national TB program is vertical, integrated or decentralized. The importance of a good management information (MIS) system is emphasized and participants acquire a good understanding of elements of a good MIS.

Session 6: Use

This session discusses the medicine use process for TB programs as based upon a variety of factors such as appropriately implemented DOTS and DOTS Plus programs, well-developed guidelines for prescribing and medicine administration, feedback on any developing resistance to the medicines and availability of quality medicines at the time patients need them. The session also emphasizes how the appropriate selection of medicine packaging such as FDCs and patient kits can positively affect patient and provider compliance and promote better patient outcomes.

Session 7: Monitoring and Evaluation

This session covers the assessment and diagnosis of pharmaceutical management systems, provides an overview of methodologies to evaluate impact of projects, and focuses on monitoring and improving performance through indicator-based methods, supportive supervision, on-the-job training, and capacity building.

The practical exercise includes a field visit to various sites of the local TB drug supply system. In preparation for the field visit, participants are challenged to think critically about the performance of pharmaceutical management systems for TB programs and the data that can be collected to make decisions regarding drug selection, procurement, distribution, availability, use and quality assurance.

Annex 4

Drug Management for Tuberculosis (DMTB) Indicators

Key Indicators

K-1. Average percentage of time out of stock for a set of TB tracer drugs in TB facilities

K-2. Average percentage of a set of TB drugs available in TB facilities and medical stores

K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines utilized

K-4. Percentage of TB drugs received in the last three shipments that were accompanied with a batch certificate

K-5. Percentage of median international price paid for a set of TB drugs that was part of the last regular procurement

Complementary Indicators

C-1. Percentage of NTP Drug Products Included on the National Essential Medicines List

C-2. Percentage of NTP Drug Products Included on the WHO Anti-Tuberculosis Essential Medicines List

C-3. Percentage of TB drug samples that failed quality-control testing out of the total number of TB drug samples tested during the past year

C-4. Percentage of TB facilities visited where the latest official manual of treatment guidelines for TB was present

C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used

C-6. Percentage of TB patients who reported regular observation of drug intake

C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer drugs in TB storage facilities

C-8. Number of days that a person has to work under reference wage to pay for a complete TB treatment course taking into account the price of drugs in the public /or private market

Annex 5

Participant Course Evaluations

	Scores	1	2	3	4	5	Total	Percent of 4 and 5's
	Overview	0	1	1	2	15	19	89.47%
Session 1	Introduction	0	0	2	3	15	20	90.00%
	Activity	0	0	3	9	8	20	85.00%
Session 2	Selection and Quantification	0	1	1	9	9	20	90.00%
	Activity	0	0	0	12	8	20	100.00%
Session 3	Procurement	0	0	1	8	11	20	95.00%
	Activity	0	1	4	7	8	20	75.00%
Session 4	Quality Assurance	0	0	2	3	15	20	90.00%
	Activity	0	1	2	6	10	19	84.21%
Session 5	Distribution	0	0	2	8	9	19	89.47%
	Activity	0	0	1	6	9	16	93.75%
Session 6	Use	0	0	4	3	13	20	80.00%
	Activity	0	0	2	7	10	19	89.47%
Session 7	Monitoring and Evaluation	0	1	2	1	16	20	85.00%
	Field Activity	0	0	0	8	12	20	100.00%
	Personal Improvement Plan	0	0	1	3	15	19	94.74%

Note on scoring:

- 1 or 2 did not meet expectations
- 3 met expectations
- 4 or 5 somewhat exceeded or exceeded expectations

General Evaluation

Question	Comment
The course had importance for my future professional responsibilities	Very important to me as manager of the program; a great deal of useful information that was well explained
The course allowed me to better understand the concepts and use of tools to better perform my duties	No comments
The course gave me the opportunity to exchange useful experiences with participants from other countries	Objectively evaluate our level and future opportunities; very little experience demonstrated by participants of other countries; needed smart discussions
The theoretical content of the presentations was useful and sufficient	No comments
The exercises and group activities were useful and sufficient	Would like room better organized and with computers; would be good to have more exercises
There was a good mix of presentations, discussions and	Was an optimal balance of theory and practice; not always enough practical work; would have liked more

Question	Comment
group activities	analysis and discussion during the last day
The duration of the course was appropriate	Exactly enough; enough as an introductory/general course
Which three activities or sessions were most useful for you, the first you list being the most useful	All sessions were useful and provided at an adequate level Introduction, practical work, management Strategies to assure quality, effective procurement strategies, types and problems with TB distribution Monitoring and evaluation, indicators Use, procurement Group work Preparing an instrument for data collection
Which three activities or sessions were the least useful for you, the first you list being the least useful	All were useful (all listed by 1 or another of the participants)
What other subjects should have been included in this course	Volume and coverage is sufficient Everything was excellent Refreshing Course for supervisors; participant presentation of procurement method in their countries; In-depth course on rational drug use Use more difficult exercises More attention to procurement More dialogues and exercises, less lectures Expand to cover drugs other than TB
What suggestions do you have to improve this course	Course was well organized and appropriately addressed our shortcomings Want more meetings like this Role play More difficult exercises